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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,574	06/11/2001	Francis Sullivan	GFN-5285D3CPACN	4282

7590

07/26/2002

Finnegan Henderson Farabow
Garrett & Dunner LLP
Attn: Leslie A. McDonell
1300 I Street NW
Washington, DC 20005-3315

EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,574

Applicant(s)

SULLIVAN ET AL.

Examiner

Yong Pak

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 9 and 21-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application is a continuation of 09/333,177, now abandoned. The preliminary amendment filed on June 11, 2001, canceling claims 1-8 and 10-20 and adding claims 21-37, has been entered.

Claims 9 and 21-37 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 9, drawn to a method of identifying an inhibitor of GM4,6D activity, classified in class 514, subclass 789.
- II. Claims 21, 26-29, drawn to a method of treating a subject having an inflammatory disorder characterized by aberrant GM4,6D activity with a modulator that comprises of an antibody against GM4,6D , classified in class 424, subclass 130.1.
- III. Claims 21, 26-28 and 30-32, drawn to a method of treating a subject having an inflammatory disorder characterized by aberrant GM4,6D activity with a modulator that comprises of the polypeptide encoded by SEQ ID NO:1, classified in class 424, subclass 94.5.
- IV. Claims 22, 26-29, drawn to a method of treating a subject having a disorder characterized by aberrant cellular fucosylation with a modulator that comprises of an antibody against GM4,6D , classified in class 424, subclass 130.1.

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- V. Claims 22, 26-28 and 30-32, drawn to a method of treating a subject having disorder characterized by aberrant cellular fucosylation with a modulator that comprises of the polypeptide encoded by SEQ ID NO:1, classified in class 424, subclass 94.5.
- VI. Claims 23, 27-29, drawn to a method for modulating an inflammatory response in a subject with a modulator that comprises of an antibody against GM4,6D , classified in class 424, subclass 130.1.
- VII. Claims 23, 27-28 and 30-32, drawn to a method for modulating an inflammatory response in a subject with a modulator that comprises of the polypeptide encoded by SEQ ID NO:1, classified in class 424, subclass 94.5.
- VIII. Claims 24, 27-29, drawn to a method for modulating cellular fucosylation in a subject with a modulator that comprises of an antibody against GM4,6D , classified in class 424, subclass 130.1.
- IX. Claims 24, 27-28 and 30-32, drawn to a method for modulating cellular fucosylation in a subject with a modulator that comprises of the polypeptide encoded by SEQ ID NO:1, classified in class 424, subclass 94.5.
- X. Claims 21 and 33-37, drawn to a method of treating a subject having an inflammatory disorder characterized by aberrant GM4,6D activity with a modulator that comprises of the nucleotide sequence of SEQ ID NO:1, classified in class 514, subclass 44.

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- XI. Claims 22 and 33-37, Claims 22, 26-29, drawn to a method of treating a subject having an disorder characterized by aberrant cellular fucosylation with a modulator that comprises of the nucleotide sequence of SEQ ID NO:1, classified in class 424, subclass 130.1.classified in class 514, subclass 44.
- XII. Claims 23 and 33-37, drawn to a method for modulating an inflammatory response in a subject with a modulator that comprises of the nucleotide sequence of SEQ ID NO:1, classified in class 514, subclass 44.
- XIII. Claims 24 and 33-37, drawn to a method for the treatment of a disease resulting from increased cell death with Invention III with a modulator that comprises of the nucleotide sequence of SEQ ID NO:1, classified in class 514, subclass 44.

If Inventions III, V, VII, or IX-13 is elected, applicants are required to further elect ONE patentably distinct nucleic acid encoding a dehydratase sequence, SEQ ID NO:2 or 3 or ONE patentably distinct dehydratase sequence encoded by SEQ ID NO:1, SEQ ID NO:2 or 3. The disclosure contains several dehydratases that are different in structure and function.

The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions (II, IV, VI and VII), (III, V, VII and IX) and (X-XIII) are patentably distinct as directed to materially different methods employing different products. Inventions (II, IV, VI and VII) use an antibodies, Inventions (III, V, VII and IX)

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use polypeptides and Inventions (X-XIII) use DNA molecules. Inventions (II, IV, VI and VII) are patentably distinct from each other because the methods have different effects and utilities. Inventions (III, V, VII and IX) are patentably distinct from each other because the methods have different effects and utilities. Inventions (X-XIII) are patentably distinct from each other because the methods have different effects and utilities. The method of Invention I is patentably distinct from Inventions II-XIII because Invention I is an in vitro method and Inventions II-XIII are vivo methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

July 25, 2002



PONNATHAPUDHUP MURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600